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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/789,367	02/26/2004	Scott D. Ganz	44928.000019	5143

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EXAMINER	
GEORGE, TARA R	

ART UNIT	PAPER NUMBER
3733	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/789,367	GANZ ET AL.	
	Examiner	Art Unit	
	TARA R. GEORGE	3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 March 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,5-95* is/are pending in the application.

4a) Of the above claim(s) *40-86* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,5-39 and 87-95* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/20/07;9/20/07;9/20/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Priority

If applicant desires to claim the benefit of a prior-filed application under 35 U.S.C. 119(e), a specific reference to the prior-filed application in compliance with 37 CFR 1.78(a) must be included in the first sentence(s) of the specification following the title or in an application data sheet. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications.

If the instant application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable

petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required. Applicant is still required to submit the reference in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

Drawings

The drawings are objected to under 37 CFR 1.83(a). **The drawings must show every feature of the invention specified in the claims. Therefore, the cutting tool,**

window template, implant base and tool for installing the implant base must be shown or the feature(s) canceled from the claim(s). No new matter should be entered. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140

F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-5, 11, 12, 14-16, 20-28 and 32-39 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 8-10, 13-26 and 29-36 of copending Application No. 10/789,358. Although the conflicting claims are not identical, they are not patentably distinct from each other because the difference between the claims is in their intended use.

The manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art or copending apparatuses satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 10-12, 14, 16, 22-24 and 26-39 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 93-102 and 104-122 of copending Application No. 10/789,439. Although the conflicting claims are not identical, they are not patentably distinct from each other

because the claims of 10/789,413 are more specific than the claims of the present application. More specific claims anticipate broader claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-16, 19-21, 23, 27, 28, 30-39, 87-92 and 95 are rejected under 35 U.S.C. 103(a) as being unpatentable over McKay (U.S. 5,972,368) in view of Boyce et al. (U.S. 6,843,807).

McKay teaches a bone graft composite comprising a demineralized bone matrix (lines 36-37 of column 9); at least one hole corresponding to either or both of an intended position of an implant base and/or an attachment device; at least one feature 19 allowing the bone graft to be held by a gripping tool; the bone graft comprising a calcium phosphate ceramic (lines 9 & 10 of column 10); further comprising channels or patterns on a surface of the bone graft (threads); further comprising bone growth factor; a resorbable polymer in the form of polylactic acid (lines 43-44 of column 9); and wherein the graft is sterile (line 59 of column 7). McKay also discloses one cutting tool in the form of a reamer, a dilator and templates (line 49 of column 11). A dilator is

incapable of cutting bone while being capable of cutting soft tissue. McKay does not appear to teach an at least partially sinus cavity shaped graft. Boyce teaches an osteoimplant shaped as an at least partially sinus cavity shaped graft (lines 5-10 and 25 of column 6). It would have been obvious to one of ordinary skill in the art at the time of the invention that bone grafts are intended to be used and thus shaped for application to several types of bone defects as taught by Boyce, who thus teaches a known technique.

Concerning the limitations of claims 2, the graft of McKay was manufactured to a shape which must have been desirable or it would not have been so manufactured.

Concerning the limitations of claims 3, 4 and 39, it is noted that the device of McKay appears to be substantially identical to the device claimed, although not disclosed as produced by the same process, therefore the burden is upon the Applicant to come forward with evidence establishing an unobvious difference between the two. In re Marosi, 218 USPQ 289 (Fed. Cir. 1983).

Concerning the limitations of claims 14 and 19, all matter, including demineralized bone and polymers is comprised of particles. For this reason, the Examiner contends that the graft comprising a matrix of particles joined to each other forming a three-dimensionally interconnected network where the particles are polymeric, is inherent to the disclosure of McKay.

As for claim 10, McKay teaches all of the limitations of the present invention except the bone graft being comprised of more than one piece. It would have been obvious to one having ordinary skill in the art at the time the invention was made to

construct the assembly of McKay having a plurality of pieces, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

As for claim 15 and 16, McKay teaches all of the limitations of the present invention except the mode of the pore size is between 10 microns and 25 microns; and the porosity being between approximately .2 and approximately .6. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the bone graft of McKay such that the mode of the pore size is between 10 microns and 25 microns; and the porosity is between approximately .2 and approximately .6., since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

As for claim 35, McKay teaches all of the limitations of the present invention except the polymer being a comb polymer. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a comb polymer in place of the polylactic acid polymer disclosed, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

As for claim 37, McKay teaches all of the limitations of the present invention except the polymer being a comb polymer. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a non-resorbable polymer in the device of McKay, since it has been held to be within the general skill of a

worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Claims 1, 14, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shimp (U.S. 6,846,853 B2) in view of Boyce (U.S. 6,843,807). Shimp teaches a bone graft suitable comprising particles of demineralized bone matrix joined to each other by a binder substance (lines 63-67 of column 3 and lines 1-5 of column 4). Shimp does not appear to teach an at least partially sinus cavity shaped graft. Boyce teaches an osteoimplant shaped as an at least partially sinus cavity shaped graft (lines 5-10 and 25 of column 6). It would have been obvious to one of ordinary skill in the art at the time of the invention that bone grafts are intended to be used and thus shaped for application to several types of bone defects as taught by Boyce, who thus teaches a known technique.

Claims 1, 14 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lo (WO 02/11781 A1) in view of Boyce et al. (U.S. 6,843,807). Lo teaches a bone graft, wherein the bone graft comprises synthetic material comprising a matrix of ceramic particles (see abstract) partially sintered directly to each other (lines 25+ of page 9) forming a three dimensionally interconnected network. Lo does not appear to teach an at least partially sinus cavity shaped graft. Boyce teaches an osteoimplant shaped as an at least partially sinus cavity shaped graft (lines 5-10 and 25 of column 6). It would have been obvious to one of ordinary skill in the art at the time of the invention

that bone grafts are intended to be used and thus shaped for application to several types of bone defects as taught by Boyce, who thus teaches a known technique.

Claims 1, 22, 24, 25 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Khandkar et al. (U.S. 2003/0009225 A1) in view of Boyce et al (U.S. 6,843,807). Khandkar et al. teaches a bone graft comprising both a nonresorbable, synthetic ceramic material and resorbable materials (in the form of a coating) in different proportions in different places within the bone graft (paragraph 0035). Khandakar does not appear to teach an at least partially sinus cavity shaped graft. Boyce teaches an osteoimplant shaped as an at least partially sinus cavity shaped graft (lines 5-10 and 25 of column 6). It would have been obvious to one of ordinary skill in the art at the time of the invention that bone grafts are intended to be used and thus shaped for application to several types of bone defects as taught by Boyce, who thus teaches a known technique.

Claims 1 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al. (U.S. 6,200,347) in view of Boyce et al. (U.S. 6,843,807). Anderson et al. teach a composite bone graft (Fig. 27), wherein the bone graft comprises demineralized bone matrix 100 in a rigid form and channels 102 which extend into an interior of the bone graft; drill 72. Anderson does not appear to teach an at least partially sinus cavity shaped graft. Boyce teaches an osteoimplant shaped as an at least partially sinus cavity shaped graft (lines 5-10 and 25 of column 6). It would have been obvious to

one of ordinary skill in the art at the time of the invention that bone grafts are intended to be used and thus shaped for application to several types of bone defects as taught by Boyce, who thus teaches a known technique.

Claims 87 and 93 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Anderson et al. and Boyce et al., as stated above, in further view of Coates et al. (U.S. 5,989,289). Anderson et al. and Boyce et al. teach a kit comprising a composite bone graft (Fig. 27) suitable to augment a sinus, wherein the bone graft comprises demineralized bone matrix 100 in a rigid form and channels 102 which extend into an interior of the bone graft; an implant base 2; a drill 72.

Hence Anderson et al. and Boyce et al. teaches all of the limitations of the present invention except a tool for installing the implant base.

Coates et al. teach a related kit which includes an implant insertion tool (Fig. 6). It would have been obvious to one of ordinary skill in the art at the time of the present invention to include an insertion tool with the elements of Anderson et al. and Boyce et al. to facilitate implantation and avoid inserting the graft by hand.

Claim 94 is rejected under 35 U.S.C. 103(a) as being unpatentable over McKay and Boyce as applied to claim 87 above, and further in view of Anderson et al. (U.S. 6,200,347). McKay and Boyce teaches all of the limitations of the present invention except an additional article in the form of antibiotics.

Anderson et al. teach a related composite bone graft which may include a pharmaceutically active agent such as antibiotic. It would have been obvious to one of ordinary skill in the art at the time of the present invention to incorporate an antibiotic agent into the graft of McKay and Boyce as taught by Anderson et al. to prevent infection at the implantation site.

Response to Arguments

Applicant's arguments with respect to claims 1-39 and 87-95 have been considered but are moot in view of the new ground(s) of rejection.

Also note that with regard to the statements of intended use and other functional statements, they do not impose any structural limitations on the claims distinguishable over any of the prior art which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. Kalman v. Kimberly Clark Corp., 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TARA R. GEORGE whose telephone number is (571)272-3402. The examiner can normally be reached on M-F from 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/T. R. G./
Examiner, Art Unit 3733
/Eduardo C. Robert/
Supervisory Patent Examiner, Art Unit 3733